

## CLAIMS

We claim:

1. An apparatus for effecting the viscosity measurement of circulating blood in a living being, said apparatus comprising:

5 a lumen arranged to be coupled to the vascular system of the being;

10 a pair of tubes having respective first ends coupled to said lumen for receipt of circulating blood from the being, one of said pair of tubes comprising a capillary tube having some known parameters;

a valve for controlling the flow of circulating blood from the being's vascular system to said pair of tubes; and

15 an analyzer, coupled to said valve, for controlling said valve to permit the flow of blood into said pair of tubes whereupon the blood in each of said pair of tubes assumes a respective initial position with respect thereto, said analyzer also being arranged for operating said valve to isolate said pair of tubes from the being's vascular system and for coupling said pair of tubes together so that the position of the blood in said pair of tubes changes, said analyzer also being arranged for monitoring the blood position change in one of said tubes and detecting a single blood position in the other one of said pair of tubes and calculating the viscosity of the blood based thereon.

20

2. The apparatus of Claim 1 wherein said apparatus is adapted for effecting the viscosity measurement of circulating blood of a living being in real-time.

3. The apparatus of Claim 2 wherein each of said tubes has a second end and whereupon said apparatus additionally comprises means for venting said second ends of said pair of tubes to the ambient atmosphere.

4. The apparatus of Claim 2 wherein said analyzer detects the change in weight of one of said pair of tubes over time to effect said monitoring of the blood position change.

5. The apparatus of Claim 2 wherein said respective initial positions comprise a first pre-test position of a first column of blood with respect to one of said pair of tubes and a second pre-test position of a second column of blood with respect to the other of said pair of tubes, said first pre-test position and said second pre-test position being different from each other.

6. The apparatus of Claim 5 wherein said pair of tubes are oriented upright and wherein said first pre-test position comprises a first initial height of said first column of blood and said second pre-test position comprises a second initial height of said second column of blood.

7. The apparatus of Claim 6 wherein said analyzer detects the change in column height of one of said first and second columns of blood.

8. The apparatus of Claim 7 wherein said analyzer detects said change in column height by detecting the time of flight of emitted signals toward the top of one of said columns.

9. The apparatus of Claim 8 wherein said emitted signals are acoustic signals.

10. The apparatus of Claim 6 wherein said analyzer includes a digital video camera for detecting the change in column height of one of said first and second columns of blood.

11. The apparatus of Claim 6 wherein said analyzer detects the change in pressure of one of said first and second columns of blood over time to effect said monitoring of the blood position change.

12. The apparatus of Claim 2 wherein said analyzer detects the change of volume in blood of one of said pair of tubes to effect said monitoring of the blood position change.

13. The apparatus of Claim 2 further comprising environmental control means, said environmental control means maintaining the blood in said capillary tube at substantially the same temperature of the living being during the time said analyzer couples said pair of tubes together.

14. The apparatus of Claim 13 wherein said environmental control means maintains the blood in said pair of tubes at substantially the same temperature of the living being during the time said analyzer couples said pair of tubes together.

15. The apparatus of Claim 5 wherein said respective initial positions of the blood in said pair of tubes is established by the operation of said analyzer.

16. The apparatus of Claim 6 wherein said first initial height and said second initial height are established by the operation of said analyzer.

17. The apparatus of Claim 5 wherein said position of the blood in said pair of tubes changes comprises the movement of a respective level of said first and second

columns of blood moving in opposite directions and wherein said analyzer determines the difference value between said respective levels.

18. The apparatus of Claim 6 wherein said position of the blood in said pair of tubes changes comprises a falling column of blood away from said first initial height and a rising column of blood away from said second initial height, said analyzer monitoring the blood position change of said rising column of blood and detecting said single blood position from said falling column of blood.

19. The apparatus of Claim 18 wherein said single blood position is said first initial height.

20. The apparatus of Claim 19 wherein said analyzer determines the difference values of said heights of said columns of blood over time, known as  $h_1(t) - h_2(t)$  wherein  $h_1(t)$  is said height of said falling column of blood and  $h_2(t)$  is said height of said rising column of blood.

21. The apparatus of Claim 20 wherein said analyzer determines an offset of said heights of said columns of blood, known as  $\Delta h$ , after monitoring the blood position change in said rising column of blood for a period of time and from said single blood position from said falling column of blood.

22. The apparatus of Claim 21 wherein said analyzer calculates the viscosity using  $h_1(t) - h_2(t)$  and  $\Delta h$  to determine the consistency index,  $k$ , and the power law index,  $n$ , as given by:

$$h_1(t) - h_2(t) - \Delta h = - \left\{ \left( \frac{n-1}{n} \right) \alpha t + (\Delta h - h_0)^{\frac{n-1}{n}} \right\}^{\frac{n}{n-1}}$$

where

$$\alpha = -\frac{1}{2} \left( \frac{4kL_c}{\rho g \phi_c} \right)^n \left( \frac{n}{3n+1} \right) \left( \frac{\phi_c^3}{\phi_r^2} \right)$$

and where

$h_0 = h_1(0) - h_2(0)$ ;

$L_c$  = length of capillary tube;

$\phi_c$  = inside diameter of said capillary tube

$\phi_r$  = diameter of said columns of blood and where  $\phi_c \ll \phi_r$

$\rho$  = blood fluid density;

$g$  = gravitational constant;

23. The apparatus of Claim 22 wherein said analyzer calculates the viscosity,

$\mu$ , using said determined values of  $n$  and  $k$  in the equation:

$$\mu = k|\dot{\gamma}|^{n-1}$$

where

$$\dot{\gamma} = \left( \frac{3n+1}{n} \right) \frac{8Q}{\pi \phi_c^3}$$

and where

$Q$  = volumetric flow rate in said capillary tube

$\phi_c$  = capillary tube diameter; and

$\dot{\gamma}$  = shear rate.

24. The apparatus of Claim 2 wherein said analyzer operates said valve to isolate said pair of tubes from the living being's vascular system while simultaneously coupling said pair of tubes together.

25. The apparatus of Claim 2 wherein said analyzer comprises a single monitor for one of said pair of tubes, said monitor monitoring the blood position change in said one of said pair of tubes.

26. The apparatus of Claim 25 wherein said monitor comprises a light array and a charge coupled device (CCD).

27. The apparatus of Claim 26 wherein said light array comprises a plurality of light emitting diodes arranged in linear fashion to illuminate said one of said pair of tubes along the length of said tube.

28. The apparatus of Claim 2 wherein said analyzer comprises a detector for detecting said single blood position.

29. The apparatus of Claim 28 wherein said detector comprises a light emitting diode and a photodetector.

30. The apparatus of Claim 2 wherein said pair of tubes is disposable.

31. The apparatus of Claim 2 wherein said valve mechanism is disposable.

32. A method for determining the viscosity of circulating blood of a living being, said method comprising the steps of:

(a) providing access to the circulating blood of the living being to form an input flow of circulating blood;

(b) dividing said input flow of circulating blood into a first flow path and a second flow path into which respective portions of said input flow pass, one of said first or second flow paths including a passageway portion having some known parameters;

(c) isolating said first and second flow paths from said input flow and coupling said first and second flow paths together so that the position of the blood in each of said flow paths changes;

(d) monitoring the blood position change in one of said first and second flow paths over time;

(e) detecting a single blood position in the other one of said first and second flow paths; and

(f) calculating the viscosity of said circulating blood based on said blood position change, said single blood position and on selected known parameters of said passageway portion.

33. The method of Claim 32 wherein said step of calculating the viscosity of said circulating blood is conducted in real-time.

34. The method of Claim 33 wherein said first and second flow paths comprise respective columns of blood in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in column height of one of said first and second columns of blood over time.

35. The method of Claim 34 wherein said step of detecting a single blood position in the other one of said first and second flow paths comprises detecting a single column height.

36. The method of Claim 34 wherein said first and second columns are vented to ambient atmosphere.

37. The method of Claim 33 wherein said first and second flow paths comprise respective columns in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in weight of one of said first and second columns of circulating blood over time.

38. The method of Claim 33 wherein said first and second flow paths comprise respective columns in upright positions and said step of monitoring the blood position change over time comprises monitoring the time of flight of emitted signals towards the top of one of said columns.

39. The method of Claim 38 wherein said emitted signals are acoustic signals.

40. The method of Claim 34 wherein said column height is monitored by a digital video camera.

41. The method of Claim 33 wherein said first and second flow paths comprise respective columns in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in pressure of one of said first and second columns of blood over time.

42. The method of Claim 33 wherein said first and second flow paths comprise respective columns in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in mass of one of said first and second columns of circulating blood over time.

43. The method of Claim 33 wherein said first and second flow paths comprise respective columns in upright positions and said step of monitoring the blood



position change over time comprises monitoring the change in volume of one of said first and second columns of blood over time.

44. The method of Claim 33 further comprising the step of maintaining the temperature of said passageway portion at substantially the same temperature of the living being during said step of monitoring the blood position change in one of said first and said flow paths.

45. The method of Claim 44 wherein said step of maintaining the temperature further comprises maintaining the temperature of said first and second flow paths at substantially the same temperature of the living being during said step of monitoring the blood position change in one of said first and said flow paths.

46. The method of Claim 34 wherein said step of dividing said input flow of circulating blood into a first flow path and a second flow path comprises establishing a first pre-test level for said first column of blood and a second pre-test level for said second column of blood, said first and second pre-test levels being different from each other.

47. The method of Claim 46 wherein said step of calculating the viscosity comprises determining difference values of said heights of said first and second columns of fluid over time, known as  $h_1(t) - h_2(t)$  wherein  $h_1$  is said height of said first column and  $h_2$  is said height of said second column.

48. The method of Claim 47 wherein said step of calculating the viscosity further comprises detecting an offset of said heights of said first and second columns, known as  $\Delta h$ .

49. The method of Claim 48 wherein said step of calculating the viscosity further comprises using  $h_1(t) - h_2(t)$  and  $\Delta h$  to determine the consistency index,  $k$ , and the power law index,  $n$ , as given by:

$$h_1(t) - h_2(t) - \Delta h = - \left\{ \left( \frac{n-1}{n} \right) \alpha t + (\Delta h - h_0)^{\frac{n-1}{n}} \right\}^{\frac{n}{n-1}}$$

where

$$\alpha = - \frac{1}{2} \left( \frac{4kL_c}{\rho g \phi_c} \right)^n \left( \frac{n}{3n+1} \right) \left( \frac{\phi_c^3}{\phi_r^2} \right)$$

and where

$h_0 = h_1(0) - h_2(0)$ ;

$L_c$  = length of said passageway portion;

$\phi_c$  = inside diameter of said passageway portion;

$\phi_r$  = diameter of said first or second column of fluid and where  $d_c \ll d_r$ ,

$\rho$  = blood fluid density;

$g$  = gravitational constant;

50. The method of Claim 49 wherein said step of calculating the viscosity,  $\mu$ , further comprises using the determined values of  $n$  and  $k$  in the equation:

$$\mu = k |\dot{\gamma}|^{n-1}$$

where

$$\dot{\gamma} = \left( \frac{3n+1}{n} \right) \frac{8Q}{\pi \phi_c^3}$$

and where

Q = volumetric flow rate in said passageway portion

$\phi_c$  = passageway portion diameter; and

$\dot{\gamma}$  = shear rate.

51. An apparatus for effecting the viscosity measurement of circulating blood in a living being, said apparatus comprising:

a lumen arranged to be coupled to the vascular system of the being;

a pair of tubes having respective first ends and second ends, said first ends being coupled together via a capillary tube having some known parameters;

a valve for controlling the flow of circulating blood from the being's vascular system to said pair of tubes, said valve being coupled to a second end of one of said pair of tubes and being coupled to said lumen; and

an analyzer, coupled to said valve, for controlling said valve to permit the flow of blood into said pair of tubes whereupon the blood in each of said pair of tubes assumes a respective initial position with respect thereto, said analyzer also being arranged for operating said valve to isolate said pair

of tubes from the being's vascular system so that the position of the blood in said pair of tubes changes, said analyzer also being arranged for monitoring the blood position change in one of said tubes and detecting a single blood position in the other one of said pair of tubes and calculating the viscosity of the blood based thereon.

52. The apparatus of Claim 51 wherein said apparatus is adapted for effecting the viscosity measurement of circulating blood of a living being in real-time.

53. The apparatus of Claim 52 further comprises means for venting said second end of said other one of said pair of tubes to atmosphere.

54. The apparatus of Claim 52 wherein said analyzer detects the change in weight of one of said pair of tubes over time to effect said monitoring of the blood position change.

55. The apparatus of Claim 52 wherein said respective initial positions comprise a first pre-test position of a first column of blood with respect to one of said pair of tubes and a second pre-test position of a second column of blood with respect to the other of said pair of tubes, said first pre-test position and said second pre-test position being different from each other.

56. The apparatus of Claim 55 wherein said pair of tubes are oriented upright and wherein said first pre-test position comprises a first initial height of said first column of blood and said second pre-test position comprises a second initial height of said second column of blood.

57. The apparatus of Claim 56 wherein said analyzer detects the change in column height of one of said first and second columns of blood.

58. The apparatus of Claim 57 wherein said analyzer detects said change in column height by detecting the time of flight of emitted signals toward the top of one of said columns.

59. The apparatus of Claim 58 wherein said emitted signals are acoustic signals.

60. The apparatus of Claim 56 wherein said analyzer includes a digital video camera for detecting the change in column height of one of said first and second columns of blood.

61. The apparatus of Claim 56 wherein said analyzer detects the change in pressure of one of said first and second columns of blood over time to effect said monitoring of the blood position change.

62. The apparatus of Claim 52 wherein said analyzer detects the change of volume in blood of one of said pair of tubes to effect said monitoring of the blood position change.

63. The apparatus of Claim 52 further comprising environmental control means, said environmental control means maintaining the blood in said capillary tube at substantially the same temperature of the living being during the time said analyzer couples said pair of tubes together.

64. The apparatus of Claim 63 wherein said environmental control means maintains the blood in said pair of tubes at substantially the same temperature of the living being during the time said analyzer couples said pair of tubes together.

65. The apparatus of Claim 55 wherein said respective initial positions of the blood in said pair of tubes is established by the operation of said analyzer.

66. The apparatus of Claim 56 wherein said first initial height and said second initial height are established by the operation of said analyzer.

5 67. The apparatus of Claim 55 wherein said position of the blood in said pair of tubes changes comprises the movement of a respective level of said first and second columns of blood moving in opposite directions and wherein said analyzer determines the difference value between said respective levels.

10 68. The apparatus of Claim 56 wherein said position of the blood in said pair of tubes changes comprises a falling column of blood away from said first initial height and a rising column of blood away from said second initial height, said analyzer monitoring the blood position change of said rising column of blood and detecting said single blood position from said falling column of blood.

15 69. The apparatus of Claim 68 wherein said single blood position is said first initial height.

20 70. The apparatus of Claim 56 wherein said analyzer determines the difference values of said heights of said columns of blood over time, known as  $h_1(t) - h_2(t)$  wherein  $h_1(t)$  is said height of said first column of blood and  $h_2(t)$  is said height of said second column of blood.

71. The apparatus of Claim 58 wherein said analyzer detects an offset of said heights of said columns of blood, known as  $\Delta h$ , after monitoring the blood position change for a period of time.

72. The apparatus of Claim 71 wherein said analyzer calculates the viscosity using  $h_1(t) - h_2(t)$  and  $\Delta h$  to determine the consistency index,  $k$ , and the power law index,  $n$ , as given by:

$$h_1(t) - h_2(t) - \Delta h = - \left\{ \left( \frac{n-1}{n} \right) \alpha t + (\Delta h - h_0)^{\frac{n-1}{n}} \right\}^{\frac{n}{n-1}}$$

where

$$\alpha = - \frac{1}{2} \left( \frac{4kL_c}{\rho g \phi_c} \right)^n \left( \frac{n}{3n+1} \right) \left( \frac{\phi_c^3}{\phi_r^2} \right)$$

and where

$h_0 = h_1(0) - h_2(0);$

$L_c$  = length of capillary tube;

$\phi_c$  = inside diameter of said capillary tube

$\phi_r$  = diameter of said columns of blood and where  $d_c \ll d_r$ ,

$\rho$  = blood fluid density;

$g$  = gravitational constant;

73. The apparatus of Claim 72 wherein said analyzer calculates the viscosity,  $\mu$ , using said determined values of  $n$  and  $k$  in the equation:

$$\mu = k |\dot{\gamma}|^{n-1}$$

where

$$\dot{\gamma} = \left( \frac{3n+1}{n} \right) \frac{8Q}{\pi \phi_c^3}$$

and where

$Q$  = volumetric flow rate in said capillary tube

$\phi_c$  = capillary tube diameter; and

$\dot{\gamma}$  = shear rate.

74. The apparatus of Claim 52 wherein said analyzer comprises a monitor for one of said pair of tubes, said monitor monitoring the blood position change in said one of said pair of tubes.

75. The apparatus of Claim 74 wherein said monitor comprises a light array and a charge coupled device (CCD).

76. The apparatus of Claim 75 wherein said light array comprises a plurality of light emitting diodes arranged in linear fashion to illuminate said tube along the length of said tube.

77. The apparatus of Claim 52 wherein said analyzer comprises a detector for detecting said single blood position.

78. The apparatus of Claim 77 wherein said detector comprises a light emitting diode and a photodetector.

79. The apparatus of Claim 52 wherein said pair of tubes is disposable.

80. The apparatus of Claim 52 wherein said valve mechanism is disposable.

81. The apparatus of Claim 51 wherein said analyzer further comprises a container, said container collecting an initial portion of the flow of circulating blood from the being's vascular system.

82. The apparatus of Claim 81 wherein said analyzer further comprises a detector adjacent an input port of said valve for detecting said initial portion of the flow of circulating blood from the being's vascular system.

83. The apparatus of Claim 82 wherein said valve isolates said container from the being's vascular system while coupling said pair of tubes to the being's vascular system.



84. The apparatus of Claim 74 wherein one of said respective monitors detects a predetermined level in one of said pair of tubes in order for said analyzer to isolate said pair of tubes from the being's vascular system.

85. A method for determining the viscosity of circulating blood of a living being, said method comprising the steps of:

(a) providing access to the circulating blood of the living being to form an input flow of circulating blood;

(b) directing said input flow into one end of a pair of tubes coupled together via a passageway having some known parameters, said input flow passing through a first one of said pair of tubes, through said passageway and into a first portion of a second one of said pair of tubes in order to form respective columns in said first and second tubes;

(c) isolating said respective columns from said input flow so that the position of the blood in each of said columns changes;

(d) monitoring the blood position change of one of said columns of blood over time;

(e) detecting a single blood position in the other one of said pair of tubes; and

(f) calculating the viscosity of the circulating blood based on said blood position change, said single blood position and on selected known parameters of said passageway.

86. The method of Claim 85 wherein said step of calculating the viscosity of the circulating blood is conducted in real-time.

87. The method of Claim 86 wherein said respective columns of blood are in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in column height of one of said columns of blood over time.

88. The method of Claim 87 wherein said step of detecting a single blood position in the other one of said pair of tubes comprises detecting a single column height.

89. The method of Claim 87 wherein one end of said pair of tubes is vented to ambient atmosphere.

90. The method of Claim 86 wherein said respective columns are in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in weight of one of said columns of circulating blood over time.

91. The method of Claim 86 wherein said respective columns are in upright positions and said step of monitoring the blood position change over time comprises monitoring the time of flight of emitted signals towards the top of one of said columns.

92. The method of Claim 91 wherein said emitted signals are acoustic signals.

93. The method of Claim 87 wherein said column height is monitored by a digital video camera.

94. The method of Claim 86 wherein said columns are in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in pressure of one of said columns of blood over time.

95. The method of Claim 86 wherein said columns are in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in mass of one of said columns of circulating blood over time.

96. The method of Claim 86 wherein said columns are in upright positions and said step of monitoring the blood position change over time comprises monitoring the change in volume of one of said columns of blood over time.

97. The method of Claim 86 further comprising the step of maintaining the temperature of said passageway at substantially the same temperature of the living being during said step of monitoring the blood position change in said respective columns.

98. The method of Claim 97 wherein said step of maintaining the temperature further comprises maintaining the temperature of said respective columns at substantially the same temperature of the living being during said step of monitoring the blood position change in one of said columns.

99. The method of Claim 87 wherein said step of directing said input flow of circulating blood into one end of a pair of tubes comprises establishing a first pre-test level for said first column of blood and a second pre-test level for said second column of blood, said first and second pre-test levels being different from each other.

100. The method of Claim 99 wherein said step of calculating the viscosity comprises determining difference values of said heights of said first and second columns of fluid over time, known as  $h_1(t) - h_2(t)$  wherein  $h_1$  is said height of said first column and  $h_2$  is said height of said second column.

101. The method of Claim 100 wherein said step of calculating the viscosity further comprises detecting an offset of said heights of said first and second columns, known as  $\Delta h$ .

102. The method of Claim 101 wherein said step of calculating the viscosity further comprises using  $h_1(t) - h_2(t)$  and  $\Delta h$  to determine the consistency index,  $k$ , and the power law index,  $n$ , as given by:

$$h_1(t) - h_2(t) - \Delta h = - \left\{ \left( \frac{n-1}{n} \right) \alpha t + (\Delta h - h_0)^{\frac{n-1}{n}} \right\}^{\frac{n}{n-1}}$$

where

$$\alpha = - \frac{1}{2} \left( \frac{4kL_c}{\rho g \phi_c} \right)^n \left( \frac{n}{3n+1} \right) \left( \frac{\phi_c^3}{\phi_r^2} \right)$$

and where

$h_0 = h_1(0) - h_2(0)$ ;

$L_c$  = length of passageway;

$\phi_c$  = inside diameter of said passageway

$\phi_r$  = diameter of said first or second column of fluid and where  $d_c \ll d_r$ ,

$\rho$  = blood fluid density;

$g$  = gravitational constant;

103. The method of Claim 102 wherein said step of calculating the viscosity,  $\mu$ , further comprises using the determined values of  $n$  and  $k$  in the equation:

$$\mu = k |\dot{\gamma}|^{n-1}$$

where

$$\dot{\gamma} = \left( \frac{3n+1}{n} \right) \frac{8Q}{\pi \phi_c^3}$$

and where

Q = volumetric flow rate in said passageway

$\phi_c$  = passageway diameter; and

$\dot{\gamma}$  = shear rate.

104. The method of Claim 85 wherein said step of providing access to the circulating blood of the living being comprises collecting a finite amount of the initial portion of said input flow of circulating blood into a container.

ADD  
A2